DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. 2005N–0017]

Medical Devices; Hematology and Pathology Devices; Reclassification from Class III to Class II of Automated Blood Cell Separator Device Operating by Centrifugal Separation Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify from class III to class II (special controls) the automated blood cell separator device operating on a centrifugal separation principle and intended for the routine collection of blood and blood components. This proposed rule would also modify the special control for the device with the same intended use but operating on a filtration separation principle. The reclassification is being proposed on FDA's own initiative under procedures set forth in FDA regulations and based on information provided to FDA. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). The agency proposes this reclassification because special controls, in addition to general controls, are capable of providing reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is

publishing a notice of availability of a draft guidance document entitled ''Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle,'' which will serve as the special control if this proposal becomes final.

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**]. See section XVI of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. 2005N–0017, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2005N–0017 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the **Comments** heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathleen E. Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish ''performance standards'' to provide such assurance. The SMDA revised the definition of class II devices to include those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such

assurance. Special controls may include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act). The SMDA also directs FDA to revise the classification of such preamendments class III devices into class I or class II or require the device to remain in class III; and directs FDA to issue a schedule for section 515(b) of the act (21 U.S.C. 360e(b)) rulemaking within 12 months of publication of a regulation retaining a device in class III. However, the SMDA does not prevent FDA from proceeding immediately to section 515(b) rulemaking on specific devices, in the interest of public health, independent of the 515(i) process.

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding

the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. Section 513(e) of the act provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d

at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Regulatory History of the Device

The automated blood cell separator device operating by centrifugal separation principle intended for the routine collection of blood and blood components is a preamendments device classified into class III. The 1976 amendments did not immediately subject preamendments devices classified in class III to the premarket approval process. The act requires FDA to publish 515(b) regulations directing the submission of premarket approval applications for preamendments class III devices. The 515(b) process involves the publication of two **Federal Register** notices, the proposed rule and the final rule. The 515(b) proposed rule announces FDA's intention to call for PMAs, lists the issues to be addressed in PMA submissions, states a deadline for the receipt of comments, and affords an opportunity to request reclassification. The final rule addresses any comments received, repeats the issues to be addressed in PMA submissions, and sets a deadline for the submission of premarket

approval applications or investigational device exemptions of not more than 90 days after the date of publication.

In the **Federal Register** of September 11, 1979 (44 FR 53050), FDA issued a proposed rule to classify into class III the automated blood cell separator device intended for routine collection of blood and blood components. The preamble to the proposed rule to classify the device included the recommendation of an FDA advisory committee, The Hematology Device Classification Panel, regarding the classification of the device.

In the **Federal Register** of September 12, 1980 (45 FR 60643), FDA issued a final rule (§ 864.9245 (21 CFR 864.9245)) classifying into class III the automated blood cell separator operating either on a centrifugal or filtration separation principle intended for routine collection of blood and blood components.

A. Centrifugal Separation Principle

In the **Federal Register** of February 19, 1988 (53 FR 5108),[1] FDA published a proposed rule to require the filing of a PMA or a notice of completion of a product development protocol (PDP) for the automated blood cell separator device based on a centrifugal separation principle and intended for the routine collection of blood and blood components. The February 1988 proposed rule summarized the risks and benefits associated with the use of the automated blood cell separator. FDA also announced an opportunity for interested persons to request a change in the classification of the device based on new information.

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[1] In the **Federal Register** of April 22, 2003 (68 FR 19766), FDA issued a withdrawal of certain proposed rules and other proposed actions; notice of intent to withdraw *Hematology and Pathology Devices; Premarket Approval of the Automated Blood Cell Separator Intended for Routine Collection of Blood and Blood Components*.

In the **Federal Register** of May 16, 1988 (53 FR 17227), FDA extended the comment period of the proposed rule from 60 days to 90 days in response to a letter from a medical trade association requesting additional time to submit comments. In response to the February 1988 proposed rule, the agency received 17 letters of comment. New information in the form of scientific evidence was submitted with several of the comments to FDA on the automated blood cell separator operating on the centrifugal separation principle. The majority of the letters of comment indicated there is sufficient evidence to provide reasonable assurance of the safety and effectiveness of the automated blood cell separator operating on the centrifugal separation principle, and supported reclassifying the device into class II when intended only for routine collection of blood and blood components. Many of the comment letters provided scientific information and references in support of the reclassification. FDA has evaluated the information submitted and decided that there is valid scientific evidence supporting a change in classification of the centrifugal-based automated blood cell separator with the intended use of routine collection of blood and blood components from class III, requiring premarket approval, to class II, requiring special controls.

Consistent with the act and regulation, FDA referred the proposed reclassification to a panel for its recommendation on the requested change in classification. FDA announced in the **Federal Register** of April 18, 1989 (54 FR 15558), that the agency would consult with the Blood Products Advisory Committee (BPAC) in an open meeting on May 11, 1989 (Ref. 1), regarding the reclassification of the automated blood cell separator operating on a centrifugal separation principle. BPAC acts in the capacity of a device classification panel for such matters as new information regarding a device and

its classification. FDA requested that BPAC consider the new information and provide its recommendation as to whether BPAC agreed that the new information was substantial and supported reclassification. The recommendation of BPAC is further discussed in section IV of this document.

In accordance with section 513(e) of the act and § 860.130(b)(1) (21 CFR 860.130(b)(1)), based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify the centrifugal-based automated blood cell separator device from class III to class II (special controls) when the intended use of the device is for the routine collection of blood and blood components. For all other uses, including therapeutic apheresis, the device remains in its current classification as class III. All therapeutic apheresis (blood cell separator) devices are regulated by FDA's Center for Devices and Radiological Health and are not part of § 864.9245.

B. Filtration Separation Principle

The automated blood cell separator device operating on a filtration separation principle and intended for the routine collection of blood and blood components is a postamendments device originally classified into class III under section 513(f)(1) of the act. On June 17, 1996, the Baxter Healthcare Corp. submitted to FDA a petition requesting reclassification from class III to class II of its AUTOPHERESIS–C SYSTEM device. The petition contained information in the form of scientific evidence to provide reasonable assurance of the safety and effectiveness of the filtration-based AUTOPHERESIS–C SYSTEM device. Consistent with section 513(f)(3) of the act and 21 CFR 860.134, FDA referred the petition to the BPAC medical devices panel for its recommendation on the requested change in classification. At a public meeting held on September 27, 1996, BPAC unanimously recommended that the

AUTOPHERESIS–C SYSTEM and subsequent membrane-based blood cell separators substantially equivalent to this device, intended for routine collection of blood and blood components, be reclassified from class III to class II. The panel believed that class II with the special controls of a periodic report filed annually for a minimum of 3 years with emphasis on adverse reactions would provide reasonable assurance of the safety and effectiveness of the device.

FDA published a notice of BPAC's recommendation in the **Federal Register** of May 29, 2001 (66 FR 29149). In this notice, FDA issued its tentative findings on BPAC's recommendation and requested from the public comments on BPAC's recommendation. The comment period closed August 13, 2001. After receiving no comments on BPAC's recommendation for reclassification or our tentative findings on BPAC's recommendation, FDA approved the reclassification petition by order in the form of a letter to the petitioner.

In the **Federal Register** of February 28, 2003 (68 FR 9530), FDA published a final rule announcing the decision to reclassify from class III to class II the filtration-based automated blood cell separator device intended for routine collection of blood and blood components (the February 2003 final rule). In addition to general controls of the act, the February 2003 final rule also provided for special controls applicable to the filtration-based devices in order to provide reasonable assurance of the safety and effectiveness of the device.

In this rule, we are proposing to change the special control listed in the February 2003 final rule for the filtration-based device. We propose the special control to be a draft guidance entitled ''Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle.'' This draft guidance, if finalized, will

provide the special controls for both filtration- and centrifugal-based automated blood cell separator devices intended for the routine collection of blood and blood components.

III. Device Description

Current § 864.9245 provides a brief description of the automated blood cell separator device operating on either a centrifugal separation principle or a filtration separation principle. The current section describes the automated blood cell separator as a device that automatically withdraws whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used for further manufacturing to prepare blood products for administration. The separation bowls of centrifugal blood cell separators may be reusable or disposable.

The current section classifies the centrifugal-based automated blood cell separator into class III (premarket approval). This proposed rule reclassification from class III to class II (special controls) applies to the automated blood cell separator device that operates by centrifugal separation principle and is intended for the routine collection of blood and blood components for transfusion or further manufacturing use. The proposed rule removes in the identification of the automated blood cell separator the words that were in parentheses—red blood cells, white blood cells, plasma, and platelets.

IV. Recommendation of the Panel

At a public meeting held on May 11, 1989, the BPAC panel considered the new information presented in the letters of comment and unanimously recommended that the centrifugal-based automated blood cell separator be reclassified from class III (premarket approval) to class II (performance

standards; now included in special controls). The panel believed that class II with performance standards (now included in special controls) would provide reasonable assurance of the safety and effectiveness of the automated blood cell separator and that there is sufficient information publicly available to establish a performance standard (special control) to assure safety and effectiveness of the device.

We believe another device classification panel recommendation is not necessary since, prior to the SMDA, a panel recommended classification into class II. If a panel recommended that a device be reclassified from class III into class II under the 1976 definition of class II, which included only performance standards as a class II control, then the panel's recommendation for class II status would not change if special controls are required that would include performance standards, among other controls. Under the SMDA, FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device.

V. Summary of Reasons for Recommendation (Reclassification)

The panel believes that the centrifugal-based automated blood cell separator device should be reclassified into class II because performance standards (special controls), in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

VI. Risks to Health

In the February 1988 proposed rule, FDA outlined its proposed findings regarding potential risks associated with the automated blood cell separator intended for routine collection of blood and blood components. FDA's

proposed findings showed the following: A major risk to health of donors is that the process of removing blood, handling the blood outside the body, and returning the blood to the donor's circulatory system could injure the cellular components of the blood and activate the body's complement system (a series of enzymatic proteins capable, when activated, of destroying intact cells). Another potential donor reaction is fever, due to a breakdown of granulocytes (leukocytes containing granules) during the pump cycle of the automated blood cell separator.

Also, if the automated blood cell separator fails to perform satisfactorily, the donor may have one or more of the following adverse reactions: (1) Shock resulting from blood loss; (2) toxic reaction to high levels of anticoagulants, such as citrate, that the automated blood cell separator adds to the blood as it is collected and before the blood is returned to the donor; (3) stress reaction due to the removal or loss of blood; (4) thrombosis due to activation of clotting factors in the blood by surfaces within the automated blood cell separator; or (5) sepsis and fever due to bacterial contamination of the blood returned to the donor.

Lastly, an unexpected or an undetected leak in the blood handling system of the device presents risks of infections to donors, patients, and operators of the device. The device presents a risk of electrical shock or injury to operators and donors if the device has an electrical malfunction. If the automated blood cell separator fails to perform satisfactorily, the blood or blood components collected from a donor may not be suitable for use because of cellular damage to blood or blood components during the collection process. One form of cellular damage is red blood cell hemolysis (destruction of the cell membrane accompanied by the release of hemoglobin).

Public comments received in response to the proposed rule indicated that the occurrence of these risks was very low, referred to ample evidence showing the safety and effectiveness of the automated blood cell separator, and supported reclassification of the device into class II.

Presently, FDA has identified the following risks associated with apheresis blood donation and processing: (1) The potential loss of blood due to leaks; (2) thrombosis due to activation of factors by foreign surfaces; (3) toxic reaction to citrate anticoagulant; (4) damage to red blood cells, activation of complement, and denaturation of proteins; (5) potential for sepsis and fever due to bacterial contamination of the donor's blood returned to the donor; (6) infectious disease risk to the donor or to the operator due to leaks; (7) electrical shock hazard; (8) donor stress reaction due to removal or loss of blood; (9) air embolism; (10) hemolysis; and (11) reservoir rupture.

In addition to the potential risks of the centrifugal-based automated blood cell separator, there is sufficient information about the benefits of the device. Extensive experience with the device indicates that the centrifugal-based automated blood cell separator is safe and effective for the intended use of routine collection of blood and blood components.

VII. Summary of Data Upon Which the Recommendation (Reclassification) is Based

In response to the February 1988 rule proposing to place the device in class III, we received 17 letters of comment from manufacturers and the blood banking community (Ref. 1 at 103). These commenters included such organizations as the Health Industry Manufacturers Association and the American Association of Blood Banks (Ref. 1 at 104). The comments received indicated the risk to benefit ratio is low. In proposing this reclassification, we

considered these industry comments and the history for over 30 years of safe use of the centrifugal-based automated blood cell separator device.

VIII. FDA's Tentative Findings

FDA believes that the special controls discussed in section IX of this document are capable of providing reasonable assurance of the safety and effectiveness of the automated blood cell separator device operating on a centrifugal separation principle with regard to the identified risks to health of this device. Based on FDA's evaluation of the additional information received in the letters of comment, as well as the 1989 BPAC panel recommendation and the safety record of the device in actual use, the agency has reconsidered the February 1988 proposed rule, and believes that the centrifugal-based automated blood cell separator device should be classified into class II (special controls). FDA, through an agency-wide action of proposed rule withdrawals (April 22, 2003, 68 FR 19766), announced its intention to withdraw the February 1988 proposed rule. Now, FDA is proposing to amend the device regulations by reclassifying from class III to class II (special controls guidance) the centrifugal-based automated blood cell separator device intended for the routine collection of blood and blood components. FDA is also changing the special control for the automated blood cell separator device using the filtration separation principle for the routine collection of blood and blood components. The same special control guidance will apply to the filtration and centrifugal-based devices when these devices are used for the routine collection of blood and blood components.

IX. Special Controls

Based on available information and in addition to general controls, FDA believes that the FDA guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Automated Blood Cell Separator Device

Operating by Centrifugal or Filtration Separation Principle,'' can provide reasonable assurance of the safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this draft guidance document.

For currently marketed products not approved under the PMA process, the draft guidance document recommends that the manufacturer file with FDA for three consecutive years an annual report on the anniversary date of the final rule for reclassification or on the anniversary date of 510(k) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the act should be included in the annual report. A manufacturer of a device that is determined to be substantially equivalent to the automated blood cell separator device operating by centrifugal or filtration separation principles intended for routine collection of blood and blood components, also would be required to comply with the same general and special controls. The firm would need to show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

The draft guidance document (special control) recommends that each annual report include, at a minimum, the following information:

- A summary of anticipated and unanticipated donor adverse device events that have occurred and that are not required to be reported by manufacturers under Medical Device Reporting (MDR).[2] We recommend summarizing and reporting donor adverse device events such as those required

[2] 21 CFR 803.1(a) — ''* * * device user facilities, importers, and manufacturers, as defined in § 803.3, must report deaths and serious injuries to which a device has or may have caused or contributed * * * .''

under § 606.160(b)(1)(iii) (21 CFR 606.160(b)(1)(iii))[3,4] to be recorded and maintained by the facility[5] using the device for the routine collection of blood and blood components. Under 21 CFR 803.50(b)(2), manufacturers are responsible for conducting an investigation of each event and evaluating the cause of the event. Therefore, this information should be available to the manufacturer to summarize and provide to FDA in the annual report. We emphasize that safety information submitted to FDA is not to be considered an admission of causation or liability (October 27, 1994, 59 FR 54046 at 54051).

- Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the act.[6]
- Any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation. Adverse reactions contributed to or caused by an apheresis blood donation device, such as operator infection or injury; equipment failures, including software, hardware, and disposable item failures; thrombosis; sepsis; and shock resulting from blood loss, may be reportable under MDR. The annual report need not include MDR reports.

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[3] Section 606.160(b) — ''Records shall be maintained that include, but are not limited to, the following when applicable: * * * (1)(iii) Donor adverse reaction complaints and reports, including results of all investigations and followup.''

[4] In a separate proposed rulemaking (Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule (68 FR 12405, March 14, 2003)), FDA has proposed amending 21 CFR 606.170 to require the investigation and recording by blood establishments of any complaint of a serious adverse reaction related to the collection or transfusion of blood or blood components.

[5] ''Facility'' means any area used for the collection, processing, compatibility testing, storage or distribution of blood and blood components (21 CFR 606.3(h)). Also, applicable is ''device user facility'' under § 803.3(f), meaning ''a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility * * *.'' (Note: The donor becomes a patient when he or she experiences and is treated for an adverse event contributed to or caused by the medical device.)

[6] For assistance see the guidance document entitled ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' January 1997, at *http://www.fda.gov/cdrh*.

X. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Blood Products Advisory Committee Meeting Transcript, May 11, 1989.

XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XIII. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental,

public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must consider alternatives that would minimize the economic impact of the rule on small entities. Reclassification of this device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act, and may permit small potential competitors to enter the marketplace by lowering their costs. Although the proposed rule special control guidance document recommends that manufacturers of these devices file with FDA an annual report for three consecutive years, this is less burdensome than the current premarket approval requirements including the submission of periodic reports (21 CFR 814.84).

The agency, therefore, certifies that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities, and no further analysis is required under the Regulatory Flexibility Act. In addition, the Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this proposed rule because the proposed rule will not impose costs of $100 million or more on State, local, and tribal governments in the aggregate, or the private sector, in any one year (adjusted annually for inflation).

XIV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

XV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XVI. Proposed Effective Date

The agency is proposing that any final rule that may issue based upon this proposed fule become effective 30 days after its date of publication in the **Federal Register**.

List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 864 be amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 864.9245 is revised to read as follows:

§ 864.9245 Automated blood cell separator.

(a) *Identification.* An automated blood cell separator is a device that uses a centrifugal or filtration separation principle to automatically withdraw whole blood from a donor, separate the whole blood into blood components, collect one or more of the blood components, and return to the donor the remainder of the whole blood and blood components. The automated blood cell separator device is intended for routine collection of blood and blood components for transfusion or further manufacturing use.

(b) *Classification.* Class II (special controls). The special control for this device is a guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle.''

Dated: March 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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